DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

January 5, 1999

Cin WL-1999-93

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John Haaga, M.D.
Chairman of Radiology
University Health Center @ Tower City Center
MK-Ferguson Plaza
1500 West 3rd St., #425
Cleveland, OH 44113

Facility I.D.#:144378

Dear Dr. Haaga:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on December 29, 1998. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. Your records lack the required information that the interpreting physician ([redacted] **M.D.)** is qualified to interpret mammograms. Your records did not demonstrate that **Dr.** [redacted] is licensed by a State to practice medicine. **[21 CFR 900.12 (a)(1)]**

2. Your records lack the required information that the interpreting physician ([redacted] **M.D.)** is qualified to interpret mammograms. Your records did not demonstrate that **Dr.** [redacted] has either board certification from any of the approved boards or two months full-time training in the interpretation of mammograms. **[21 CFR 900.12 (a)(1)]**

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. There were no records or attestations regarding the initial training of 40 hours of continuing medical education in mammography for the interpreting physician, [redacted] **M.D. [21 CFR 900.12 (a)(1)]**

2. There were inadequate records or attestations regarding the interpreting physician's initial experience reading and interpreting mammograms of at least 240 patients in six months for the interpreting physician, [redacted] **M.D. [21 CFR 900.12 (a)(1)]**

The other items listed in your December 29, 1998 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address these Level 3 items in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to $10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.

- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.

- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to **correct** all of the violations noted in this letter;

- each step your facility is taking to **prevent the recurrence** of similar violations;

- sample records that demonstrate proper record keeping procedures, if the noncompliance items that were found relate to quality control or other records **(Note: Patient names or identification should be deleted from any copies submitted).**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.